DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NORAS MRI Products GmbH
% Mr. Zahed Sedighiani
Quality and Regulatory Management
Leibnizstrasse 4
Hoechberg D-97204
GERMANY

August 6, 2014

Re: K133506
Trade/Device Name: NORAS OR Head Holder "Flexibility"
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS, HBL
Dated: June 25, 2014
Received: June 27, 2014

Dear Mr. Sedighiani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133506

Device Name
NORAS OR Head Holder Flexibility 114464

Indications for Use *(Describe)*

For Siemens:

The NORAS OR Head Holder Flexibility and the NORAS OR Head Coils 1.5T / 3.0T are used for intra-operative MR imaging during open-skull neurosurgery.
The NORAS OR Head Holder is used for safely securing the patient's head during the intervention.
The NORAS OR Head Holder Flexibility together with the NORAS OR Head Coil 1.5T / 3.0T are suitable for use with the MR system MAGNETOM Aera / Skyra and the Combi-Dockable-Table together with Trumpf OR Tables TrueSystem 7500 (EU/US Version) and as well as together with Maquet OR Tables Magnus (EU/US Version) and Alpha Maquet Plus (EU/US Version).

For Philips:

The NORAS OR Head Holder Flexibility and the NORAS OR Head Coils 1.5T / 3.0T are used for intra-operative MR imaging during open-skull neurosurgery.
The NORAS OR Head Holder is used for safely securing the patient's head during the intervention.
The NORAS OR Head Holder Flexibility together with the NORAS OR Head Coil 1.5T / 3.0T are suitable for Philips MR system Ingenia 1.5T/3T in combination with Maquet Transfer Board together with Maquet OR table.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

NORAS OR Head Holder Flexibility

Date of Summary Preparation: March 28, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

1. General Information

Importer/Distributor

Name and Address

NORAS MRI products GmbH

Leibnizstr.4

97204 Hoechberg / Germany

ERN: 3004929307

Owner/Operator Number: 9071737

Manufacturing Site

Name and Address

NORAS MRI products GmbH

Leibnizstr.4

97204 Hoechberg / Germany

ERN: 3004929307

Owner/Operator Number: 9071737

2. Contact Person

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zahed.sedighiani@noras.de

3. Device Name and Classification

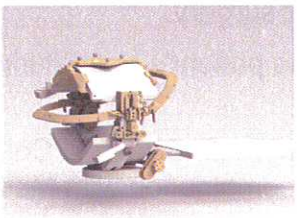
Trade Name:	**NORAS OR Head Holder Flexibility**
Common Name:	**NORAS OR Head Holder Flexibility**
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
CFR Number:	21 CFR § 892.1000
Device Class:	II
Product Code:	MOS, HBL

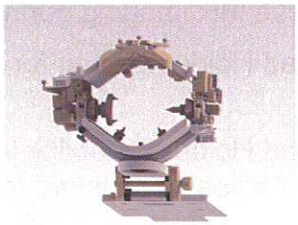
4. Device Description

The NORAS OR Head Holder and the NORAS OR Head Coil 1.5T / 3.0T combine the functions of a head holder for neurosurgical interventions and an MR receiving coil for intra-operative surgery.

The NORAS OR Head Holder without the NORAS OR Head Coil 1.5T / 3.0T can be used for stabilizing the patient's head. It can also be used in combination with the body coil.

The Head Frame of the NORAS OR Head Holder allows adjustment to heads varying in size. For optimal access to the area of intervention, the Head Frame can be swiveled and rotated.





5. Indications for Use

For Siemens:

The NORAS OR Head Holder Flexibility and the NORAS OR Head Coils 1.5T / 3.0T are used for intra-operative MR imaging during open-skull neurosurgery.

The NORAS OR Head Holder is used for safely securing the patient's head during the intervention.

The NORAS OR Head Holder Flexibility together with the NORAS OR Head Coil 1.5T / 3.0T are suitable for use with the MR system MAGNETOM Aera / Skyra and the Combi-Dockable-Table together with Trumpf OR Tables TrueSystem 7500 (EU/US Version) and as well as together with Maquet OR Tables Magnus (EU/US Version) and Alpha Maquet Plus (EU/US Version).

For Philips:

The NORAS OR Head Holder Flexibility and the NORAS OR Head Coils 1.5T / 3.0T are used for intra-operative MR imaging during open-skull neurosurgery.

The NORAS OR Head Holder is used for safely securing the patient's head during the intervention.

The NORAS OR Head Holder Flexibility together with the NORAS OR Head Coil 1.5T / 3.0T are suitable for Philips MR system Ingenia 1.5T/3T in combination with Maquet Transfer Board together with Maquet OR table.

6. Substantial Equivalence

NORAS MRI products GmbH believes that, within the meaning of the Safe Medical Devices Act of 1990, the **NORAS OR Head Holder Flexibility** is substantially equivalent to the following OR Head Holder:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Product Code	Comparable Properties
NORAS OR Head Holder	K071179	April 27-2007	MOS, HBL	Fixation of the patient's head

7. Summary of Technological Characteristics of the Principal Device as Compared with the predicate Device

In comparison to the existing OR head holders, the OR Head Holder Flexibility PN: 114464 includes only some minor mechanical changes which contribute to more flexibility in patient positioning. According to our internal evaluations as well the external tests done by VDE the new components such as Z-joint meet the requirements of IEC 60601-1 3.ed (clause 9.8) and do not adversely affect the safety of the design.

8. General Safety and Effectiveness Concerns

The **NORAS OR Head Holder Flexibility** combined with the **NORAS OR Head Coil 1.5T / 3T** will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the IEC standards for safety issues with the Magnetic Resonance Imaging Devices, IEC 60601-2-33:2002. This will assure that the performance of this device can be considered safe and effective when used with the currently available Siemens MAGNETOM Aera/Skyra 1.5T/3T as well as Philips Ingenia 1.5T/3T systems.

9. Conclusion as to Substantial Equivalence

NORAS MRI products GmbH believes that, within the definition of the Safe Medical Devices Act of 1990, the **NORAS OR Head Holder Flexibility** is substantially equivalent to the predicate device listed above.

Zahed Sedighiani
Quality and Regulatory Affairs Manager

June 25, 2014